

CLAIMS

1. A spore which is genetically modified with genetic code comprising at least one genetic construct encoding a therapeutically active compound and a targeting sequence or a vegetative cell protein
2. A spore as claimed in Claim 1 characterised in that the therapeutically active compound is an antigen or a medicament or a precursor to an antigen or a medicament.
3. A spore as claimed in Claim 1 or Claim 2 characterised in that the gene construct is a chimeric gene.
4. A spore as claimed in any one of the preceding Claims characterised in that the spore is of *Bacillus* or *Clostridia*.
5. A spore as claimed in any one of the preceding Claims characterised in that the genetic modification is accomplished by transformation of a mother cell using a vector containing the gene construct and then inducing the mother cell to produce spores as defined in any one of the preceding Claims.
6. A spore as claimed in any one of the preceding Claims characterised in that the gene construct is under the control of one or more of, each or independently, an inducible promoter, a promoter or a strong promoter or modified promoter.
7. A spore as claimed in Claim 6 characterised in that the gene construct has an enhancer element or an upstream activator sequence associated with it.

8. A spore as claimed in any one of the preceding Claims characterised in
2 that the construct comprises an inducible expression system.

9. A spore as claimed in any one of the preceding Claims characterised in
2 that the spore germinates in the duodenum and/or the jejunum of an intestinal
tract of a human or animal body.

10. A spore as claimed in any one of the preceding Claims characterised in
2 that the therapeutically active compound is an antigen which, in use, is
adapted to elicit an immune response.

11. A spore as claimed in Claim 10 characterised in that the antigen is at
2 least a fragment of tetanus toxin fragment C or labile toxin B sub unit.

12. A spore as claimed in any one of the preceding Claims characterised in
2 that the protein is a protein that is expressed in the cell barrier.

13. A spore as claimed in any one of the preceding Claims characterised in
2 that the protein is expressed all the time in a vegetative cell.

14. A spore as claimed in Claim 13 characterised in that the protein is
2 OppA or rrnO.

15. A spore as claimed in any one of Claims 1 to 12 characterised in that
2 the protein is expressed intermittently in a vegetative cell.

16. A spore as claimed in any one of Claims 1 to 11 characterised in that
2 the protein is a soluble cytoplasmic vegetative cell protein.

17. A spore as claimed in Claim 16 characterised in that the protein is rrnO.

18. A spore as claimed in Claim 16 or Claim 17 characterised in that the
2 genetic construct of the soluble cytoplasmic protein wholly or partially
comprises a signal sequence.

19. A spore as claimed in any one of Claims 1 to 11 characterised in that
2 the signal sequence is adapted to target the therapeutically active compound to
a specific part of the vegetative cell.

20. A spore as claimed in Claim 19 characterised in that the signal
2 sequence directs the therapeutically active compound for secretion (preferably
active secretion, more preferably Type I, Type II or Type III secretion), or for
4 post-translational processing by a vegetative cell (preferably glycosylation).

21. A spore as claimed in any one of the preceding Claims characterised in
2 that the therapeutically active compound is an antigen precursor which is one
or more enzymes capable of transforming a biological precursors, such that
4 upon germination said one or more enzymes are expressed and synthesise one
or more antigens by transformation of a said biological precursor.

22. A spore as claimed in Claim 21 characterised in that the biological
2 precursor is a hormone, a steroid hormone, a painkiller or a pro-drug.

23. A spore as claimed in any one of Claims 1 to 20 wherein the
2 therapeutically active compound is a medicament which is a protein, a vaccine
or an endorphin.

24. A spore as defined in any one of the preceding Claims characterised in
2 that it is for use in treatment of a medical condition, preferably the medical
condition is inflammation, pain, a hormonal imbalance and/or an intestinal
4 disorder.

25. A composition comprising at least two different spores as defined in
2 any one of the preceding Claims characterised in that said at least two
different spores express at least two different therapeutically active
4 compounds.

26. A composition as defined in Claim 25 characterised in that the
2 composition further comprises a pharmaceutically acceptable excipient or
carrier.

27. A composition comprising a spore as defined in any one of claims 1 to
2 24 in association with a pharmaceutically acceptable excipient or carrier.

28. A composition as defined in any one of Claims 25 to 27 for use in
2 treatment of a medical condition, preferably the medical condition is
inflammation, pain, a hormonal imbalance and/or an intestinal disorder.

29. Use of a spore as defined in any one of claims 1 to 24 in the
2 manufacture of a medicament for use in the treatment of a medical condition,
preferably the medical condition is inflammation, pain, a hormonal imbalance
4 and/or an intestinal disorder.

30. A method of medical treatment, which method comprises the steps of
2 a) administering a spore as defined in any one of claims 1 to 24 to a
human or animal in need of medical treatment;

- 4 b) said spore germinating into a vegetative cell in the intestinal
 tract;
- 6 c) said vegetative cell expressing a therapeutically active compound
 for use in the medical treatment.

31. A method as claimed in Claim 30 characterised in that the spore is
2 administered orally, intra-nasally or rectally.